

# **EXHIBIT AA**

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# **Meshes in Pelvic Floor Repair**

**Findings from literature review and  
interviews with surgeons**

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Kathy,  
this should be included in the  
Gynecology PS DTF (A 0956).  
If possible, it belongs to the  
P.D.D. (Section 7) following  
the marketing research pages.  
Call me if you have any questions!  
Karin Elbert x2057

## Contents

<b>1. Summary and Conclusions</b>	
1.1 Rationale of using mesh implant	1
1.2 Experience with Prolene / Gynemesh	2
1.3 Conclusions	3
<b>2. Findings from the literature review</b>	4
2.1 Epidemiology	4
2.2 Classification	5
2.3 Normal pelvic floor physiology	5
2.4 Pathophysiology / etiology of pelvic prolapse	5
2.5 Anterior vaginal wall prolapse (cystocele)	6
2.5.1 Vaginal approach	7
2.5.2 Abdominal / laparoscopic approach	8
2.6 Posterior vaginal wall repair (rectocele)	8
2.7 Vaginal vault prolapse	9
2.7.1 Vaginal approach	9
2.7.2 Abdominal approach	9
2.8 Experience with meshes in pelvic floor repair	10
2.8.1 Nonabsorbable meshes	10
2.8.2 Composite meshes	11
2.8.3 Absorbable meshes	11
<b>3. Annex : Literature References</b>	12

**Ethicon GmbH  
R&D Europe**

## **Meshes in Pelvic Floor Repair**

### **Findings from literature review and interviews with surgeons**

#### **1. Summary and Conclusions**

This report is based on findings from in-house data, from 62 publications on pelvic floor repair, including studies on the use of mesh implants, and from interviews with 23 surgeons from US, UK, Sweden, Finland, France, Italy, The Netherlands and Germany.

It appears that there is no internationally recognized gold standard procedure for treatment of pelvic floor defects. Abdominal, laparoscopic and vaginal approaches are all common, the latter being predominant and also the most attractive one for a mesh repair concept for its procedural simplicity.

Pelvic floor prolapse has different clinical manifestations:

- Anterior vaginal wall prolapse
- Posterior vaginal wall prolapse
- Prolapse of the vaginal vault
- Stress urinary incontinence

These clinical manifestations often appear combined and may then be treated in one operation, through multiple procedures. The National Center for Health Statistics, figures for 1987, report that nearly 400,000 operations are performed annually for pelvic organ prolapse and stress urinary incontinence (24457). About 70% of all pelvic floor prolapse repairs are repairs of the anterior vaginal wall prolapse.

#### **1.1 Rationale of using mesh implant :**

It was observed that even with extending the procedure from traditional anterior and posterior colporrhaphy to include additional procedures such as needle urethropexy, bilateral transvaginal paravaginal defects repairs, sacrospinous ligament fixation or prespinous repair, enterocele repair or prophylaxis, the recurrence rate still was 20% (20827). This clearly demonstrates that there is a clinical need for improvement of current techniques.

Using a mesh implant therefore targets at reducing the recurrence rate, but there are also additional aims, namely to (24589)

- Create a tension-free repair
- Minimize postoperative pain
- Minimize difficulty in defecation (rectocele repair)
- Avoid stenosis and dyspareunia

The rationale of colporrhaphy technique is to repair the defect by creating a thin scar which will then restore the original function of the tissue. To buttress the repair additionally mesh implants – non-absorbable, composite and absorbable - have been used for repair of prolapse stage III or IV for second or more recurrence, but are generally not recommended for primary repairs, because there is concern to use mesh implants in view of the observed mesh-related complications (22210):

- Erosions in abt. 10% (more when ePTFE was used)
- After sling procedures up to 35% removal rate (Gore-Tex)
- 10% sinus tract formation (Gore-Tex)
- Urethral erosion 4% (Marlex)
- Fistula (1.4%)
- Mesh removal 6%
- Overall revision and removal rate among 961 synthetic suburethral slings of 7,3% (22210).
- Overall revision and removal rate among 592 sacrocolpopexie of 2,7%.

Out of the 23 surgeons interviewed, 11 already had used meshes for pelvic floor repair , 8 of them for anterior vaginal wall (cystocele) repair, another 3 for colposacropexy or posterior vaginal wall repair, but not for cystocele repair. All of them had experience with Prolene Mesh or Gynemesh.

Those who had used Prolene mesh or Gynemesh mentioned the following advantages and disadvantages:

## **1.2 Experience with Prolene/Gynemesh**

Advantages:

- Well tolerated, inert
- No late infection encountered
- Good tissue incorporation
- No need to explant mesh in case of exposure
- If mesh exposed, treatment by excision of exposed mesh area and re-suturing mucosa over it, has proven adequate and successful therapy.

Disadvantages:

- Too thick and bulky
- Too stiff
- Releases particles when cut
- Erosion rate similar to other synthetic meshes

### **1.3 Conclusions**

The repair concept using a mesh implant is plausible.

A mesh thinner than the current Prolene mesh and with some elasticity would be well accepted. Vypro would meet these requirements. A totally nonabsorbable mesh with similar mechanical properties as Vypro would also be well accepted.

## 2. Findings from the literature review

This review is based on 62 international publications. That broad search revealed 95 publications out of which only 16 dealt with pelvic floor repair (cystocele, rectocele, vaginal vault prolapse).

Pelvic floor prolapse is the general term used to describe various clinical conditions associated with pelvic floor relaxation in female patients (24784). These conditions are considered most difficult to diagnose and treat (24191). Their clinical manifestations are:

- Stress urinary incontinence
- Anterior vaginal wall prolapse (medial and / or lateral cystocele)
- Posterior vaginal wall prolapse (rectocele)
- Vault prolapse (Enterocoele, uterine prolapse, vaginal vault prolapse)

In a high percentage, these clinical manifestations are combined. Therefore, combined approaches such as colposacropexy plus anterior and posterior colporrhaphy are common.

### 2.1 Epidemiology

National Center for Health Statistics, figures for 1987, report that nearly 400,000 operations are performed annually for pelvic organ prolapse and stress urinary incontinence (24457). Since there is no distinction between these clinical manifestations, it is not clear what percentage of the 400,000 refers to the cure of anterior or posterior vaginal wall prolapse. The estimated frequency of vaginal vault prolapse is 5% of all hysterectomies (= 60,000 cases worldwide).

Estimates suggest that 50% of parous women have some degree of genital prolapse, but that only 10-20% of the cases are significant enough to cause symptoms. (24625)

In a British region, the annual incidence of hospital admission with prolapse before 60 years of age was 2 % per 1000 person-years (24197 Ref. 2)

Samuelsson et al.(24197) who studied the prevalence of genital prolapse in a general population of Swedish women 20 to 59 years of age , with 487 women recruited for the study, found the highest prevalence (abt. 55 %) in the age group 50 to 59 years. 44% of parous women of the studied ages had some form of prolapse, but only 1.6% had a prolapse that reached the introitus when straining. No woman from this population had a prolapse which would correspond to stage III or IV of the terminology proposed by Bump et al (24314).

## 2.2 Classification

Pelvic floor prolapse is classified in the following stages (24314):

Stage	
0	No prolapse demonstrated
I	Most distal portion of the prolapse is more than 1 cm above the level of the hymen
II	Most distal portion of prolapse is less or equal to 1 cm proximal to or distal to the plane of the hymen
III	Most distal portion of the prolapse is more than 1 cm below the plane of the hymen but protrudes no further than 2 cm less than the total vaginal length in centimeters
IV	Complete eversion of the total length of the lower genital tract. In most instances, the leading is the cervix or vaginal cuff scar

## 2.3 Normal pelvic floor physiology:

The levator muscle plate is nearly horizontal

There is a double muscular layer in the area of most stress

When the abdominal pressure rises, the muscles of the pelvic floor contract to increase the closure pressure of the urethral and anal sphincters.

This supportive function of the muscles relieves the stress on the ligaments / connective tissue layers / fascial structures

In the normal strong and well supported pelvic floor, changes in intra-abdominal pressure are properly and equally transmitted to the intra-abdominal viscera, including urethra and bladder. Pelvic floor relaxation, however, will not allow proper transmission of intra-abdominal pressures to the bladder and urethra because of dampening effect of the convex, lax pelvic floor (24785).

## 2.4 Pathophysiology / etiology of pelvic prolapse

Prolapse occurs when the musculofascial support system of the pelvic organs becomes weakened or damaged. When the muscles are weakened, the stress on the ligamentous structures becomes more intense, thus leading to their over-extension and finally to their deterioration.

Due to the hydrostatic pressure when standing upright, the pressure is highest on the lowest pole = on the pelvic floor, but its surface is small and thus does not bear the whole pressure exerted by the section of the intestinal cylinder.

The essential forces that hold the intestinal cylinder and that relieve the pressure from the pelvic floor are the suction effect of the lungs and the tension of the abdominal wall muscles. Consequently, the pelvic floor faces most unfavourable conditions with a small thorax and atrophied abdominal wall muscles. With diastasis of the levator ani muscles and connective tissue that connects them to the lateral walls of the vagina (24802), the hiatus genitalis becomes the hernial orifice for the inner genitals.

Underlying causes of pelvic floor defects : (24191, 24732)

- intrinsic defects, mainly weakness of tissue collagen
- mechanical trauma / damage to the pelvic floor and its nerve supply during childbirth (above all, vaginal delivery of big children is considered a risk factor)
- Injury of nerval structures
- Hysterectomy
- Estrogen insufficiency (receptors expressed in the squamous epithelium of the proximal and distal urethra, vagina, trigone of the bladder, pubococcygeus muscles)
  - Cascade of events in oestrogen deficiency:
    - Reduced tissue vascularity
    - Decreased glycogen content of epithelial cells
    - Fall in lactobacilli content
    - Increase of pH
    - Other bacterial including coliforms grow
    - Irritation, discharge
    - Atrophy of vaginal epithelium
  - Presenting symptoms: Vaginal dryness, soreness, dyspareunia
- Influence of aging:
  - Connective tissue becomes more elastic .
  - Abdominal wall and pelvic floor muscles undergo atrophic changes
  - Less energy is required to produce irreversible damage .
- Chronic increases in intraabdominal pressure (obesity, chronic lung disease, occupational straining, constipation (24625)

The usual symptoms associated with genital prolapse are the following (24457)

Protrusion of tissue	>90
Pressure	>90
Impaired coitus	37
Voiding difficulty	33
Urinary incontinence	33
Walking difficulty	25
Difficulty in defecating	25
Pelvic pain	17

## 2.5 Anterior vaginal wall prolapse (cystocele)

Anterior vaginal wall prolapse is defined as pathologic descent of the anterior vaginal wall and overlying bladder base.

As Weber points out (G-28, p. 211) there has never been a systematic or comprehensive description of anterior vaginal prolapse based on physical findings and correlated with findings at surgery to provide objective evidence for any of the theories on pathologic anatomy. Improvements in diagnostics such as MRI may lead to a greater understanding of normal pelvic anatomy and the abnormalities associated with prolapse.

Asymptomatic patients with grade 1 or 2 cystoceles isolated do not usually require treatment. The surgical approach is perceived as necessary in grade III and IV cystocele (grading according to classification mentioned above). These large cystoceles may result from weakness of the levator hiatus with resulting laxity of the pubocervical fasciae and separation of the cardinal ligaments (24785). They are considered a significant clinical problem and difficult to manage (24787). About 1/3 of patients with large cystocele typically have masked concomitant urinary incontinence that can be detected by urodynamic evaluation and by inserting a vaginal pack or a temporary pessary device simulating the reduced cystocele. Of the other two thirds, about 50% will most likely develop stress incontinence later on. This is the reason why surgeons recommend to choose combinations of pubovaginal slings with anterior colporrhaphy as treatment of choice (24785, 24787).

### **2.5.1 Vaginal approach**

The anterior colporrhaphy (including Kelly plication) using the vaginal approach is considered the standard for cystocele repair (24785) by many gynecologic surgeons.

Surgical technique : multiple interrupted absorbable sutures (e.g. Vicryl) from the vaginal cuff to approximately the level of the bladder neck (2 cms away from the bladder neck, if a pubovaginal sling is performed additionally (24191). The sutures should not be placed too far laterally, as this would place undue tension on the fascia, which is relatively fixed at the arcus tendineus and not too deeply since inadvertent intrusion into the bladder or obstruction of the ureters can occur .

The vaginal repair is also the approach of choice when there is a need to address both, anterior and posterior vaginal wall prolapse, additionally accompanied by incontinence. Surgery may then be performed by a combined bladder suspension technique, anterior and posterior colporrhaphy.

Few studies have addressed the long-term success of surgical treatment of anterior vaginal wall prolapse. No controlled studies have compared different procedures performed primarily for anterior vaginal wall prolapse (G-28, p.219). Long term results are also difficult to compare because of significant differences in technique, different definitions of failure and different indications for the procedure, many anterior colporrhaphy procedures being performed for urinary incontinence and not cystocele (24191, 24457).

According to Dr. Petri (personal communication, March 15, 2000), a recent survey carried out in Germany demonstrated that more than 60 % of the gynecologists still perform a hysterectomy combined with anterior and posterior colporrhaphy to treat stress urinary incontinence, though several authors have pointed out that this procedure should be abandoned as treatment of stress urinary incontinence, for unsatisfactory long-term results.

The anterior vaginal segment is considered the most common site for recurrent pelvic support defects , failure rates amounting to 20-40% (20827, 9087) are a disappointing result. Apart from recurrence, these are the complications of anterior vaginal wall repair reported: Erosion, draining sinuses, chronic areas of vaginal granulation tissue if permanent sutures or mesh materials are used , voiding difficulty. Also, repair of one vaginal compartment may predispose another compartment to the development of prolapse, e.g. anterior wall repair may cause rectocele to develop (24457).

Although the vaginal approach to cystocele is common, vaginal anterior colporrhaphy addressing only the medial defect may be insufficient if also lateral defects are present as this will lead to recurrence (24780). Some surgeons therefore claim the importance of correctly diagnosing the lateral defects suggesting to treat isolated paravaginal defects by transabdominal or laparoscopic repair (24780).

### **2.5.2 Abdominal / laparoscopic approach**

Several abdominal colposuspension and bladder neck procedures have been described in cystoceles combined with stress incontinence (12735, 13095, 17045, 24398, 24399) using absorbable (chromic catgut) and non-absorbable sutures (Prolene, Nylon).

Advocates of the paravaginal repair, performed transvaginally, laparoscopically or abdominally (24780, 24781) claim that plication of the pubocervical fascia in the midline – as in anterior colporrhaphy combined with Kelly plication – actually increases the paravaginal defect by pulling the anterolateral vaginal sulcus even further from the arcus tendineus (white line).

Paravaginal repair, on the other hand, is perceived as good for support of the urethra and lateral bladder wall. It may fail, however, because it does not correct the central herniation of the bladder. Another disadvantage is the laparotomy with its increased morbidity and longer hospital stay compared with the vaginal approach.

It is also important to note that the Burch colposuspension is complicated by a high incidence of genital prolapse, rectocele and enterocele (15553).

For severe anterior vaginal wall prolapse (grade IV cystourethrocele), Raz et al (24785) and Cross et al. (24787) recommend a combination of bladder suspension and anterior colporrhaphy.

### **2.6 Posterior vaginal wall repair (rectocele)**

Rectocele is characterized by an outpocketing of the anterior rectal and posterior vaginal wall into the lumen of the vagina (24458). It is frequently detected when patients undergo diagnostics for constipation. Other symptoms caused by a rectocele are: sensation of rectal pressure, incomplete rectal emptying, vaginal symptoms from the herniation into the vaginal wall such as sensation of a vaginal mass, dyspareunia, decreased sensation during intercourse (24784).

Posterior vaginal wall prolapse is most commonly repaired using a posterior colporrhaphy (24195) which is predominantly performed vaginally (24460, 22209, 22211).

Principle of vaginal technique: Excess vaginal skin is excised and the underlying connective tissue and levator muscles plicated before closure of the skin. There is, however, concern with the adverse effect of this procedure on sexual function because of the high vaginal stenosis rate and resulting dyspareunia (20%, 24458). This had led to the search for alternative methods of repair, such as mesh repair, laparoscopic approaches and rectal repair (24637, 24459, 24460, 24461), although there is debate on the latter, as the defect is considered a vaginal defect, not a rectal one (24637).

The literature search has revealed the following studies, on the use of meshes:

Vicryl mesh - laparoscopic approach (24637)  
Polyglycolic acid mesh – vaginal approach (24746)  
Marlex mesh – transperineal approach (20288)  
Prolene mesh – vaginal approach (22211)

## 2.7 Vaginal vault prolapse

Vaginal vault prolapse is a complication of abdominal or vaginal hysterectomy or other pelvic surgery and occurs in up to 5% (18456, 24195, 24732).

It is frequently combined with cystocele, rectocele, enterocele and urinary stress incontinence. (24180).

There are three main surgical techniques addressing this complication.

### 2.7.1 Vaginal approach

Vaginal sacrospinous fixation (sacrospinous ligament fixation) using various absorbable (Vicryl, Dexon, Maxon, PDS) or nonabsorbable (Prolene, Ethibond) sutures or mesh slings (Marlex, Prolene, Mersilene, Gore-tex)

(12108, 1188, 8827, 15548, 24180, 1189, 22265, 12108, 18548, 20827). The advantage of sacrospinous fixation, compared to sacrocolpopexy, is its easy combination with other prolapse repair such as cystocele and particularly rectocele which is virtually impossible to repair using the abdominal approach. (24732)

### 2.7.2 Abdominal approach

The abdominal approach – sacrocolpopexy or sacropexy – is also common using the same suture materials as for sacrospinous fixation. Its major disadvantage is the increased morbidity associated with a laparotomy (24732).

Several authors have reported on their experience using various meshes or other grafts for abdominal sacrocolpopexy:

Mersilene mesh (157, 9644, 12470, 15269, 15548, 22210, 22263, 24099)

Teflon / Gore-tex strips (12426, 15548, 16160, 22144, 22210, 22491, 24099)

Prolene mesh (12873, 16505, 20017, 22211)

Marlex mesh (16160, 22210)

Vicryl polyester mesh (20414)

Vicryl mesh (18548)

Lyodura (5883, 22144) Complications with grafts presented as

Mesh rejection in 2 to 20% (24099, 15548, 22210)

Fistula in 1.6 to 4.5% (16160, 22210)

Mesh erosion in 5.1 to 11 % (22210)

Discharge in 8.7 (22210)

Infection in 2.4 to 7.7% (22210)

There have also been reports on laparoscopic sacrocolpopexy (16505, 18548, 20017, 22211). The success rate of sacrocolpopexy is quoted at 68 to 100 % (24732).

There is evidence that sacrocolpopexy is associated with a slightly longer functional vaginal length as compared to sacrospinous fixation. (24732).

The vaginopexy (Williams-Richardson) is performed by suspending the vagina from the external oblique muscle using fascial strips (5883, 7279, 8827, 20773, 23703). This method is not as popular as the two others described earlier.

As vaginal vault prolapse is frequently combined with cystocele, rectocele, enterocele and urinary stress incontinence, additionally anterior and posterior colporrhaphy, urethropexy, hysterectomy are performed.

## **2.8 Experience with meshes in pelvic floor repair**

Iglesia et al (22210) carried out an Ovid search of the English literature on the use of mesh in gynecologic surgery, together with a hand search of Index Medicus from 1950 to 1965.

All studies on mesh identified consisted of retrospective case series (21x suburethral sling, 15 x sacrocolpopexy articles, 5 x pelvic sling). No randomized prospective trials were available.

Apart from using meshes as slings for procedures to treat stress incontinence, meshes have been used in pelvic floor repair, predominantly for abdominal sacrocolpopexy and vaginal sacrospinous fixation, to a lesser extent for rectocele and cystocele repair.

### **2.8.1 Nonabsorbable meshes**

For cystocele combined with stress incontinence, Nicita (24802) has used a nonabsorbable mesh cut in a hammock shape. The mesh is fixed to the bladder neck, to the cervix and laterally to openings through pubic bone insertions of the arcus tendineus.

Nicita mentions that the lateral edges of the mesh could also be fixed to the abdominal rectus muscles.

Julian (20827) compared the results of 12 patients treated with Marlex mesh to a group of 12 patients without mesh, both groups with two or more postsurgical recurrences of severe anterior vaginal wall prolapse. Apart from the mesh implant, both patient groups underwent the same combined procedure consisting of Pereyra urethropexy, anterior colporrhaphy, bilateral transvaginal and paravaginal defect repairs, sacrospinous ligament fixation or prespinous fixation, enterocele and rectocele repair. At two years follow-up, there were four cases of recurrent prolapse of the anterior vaginal segment in the control group and none in the treatment group.

However, there were three long-term graft complications, all noted within 6 months of surgery, the most significant being a 0.5 cm opening below the graft that caused abnormal discharge. To prevent this type of erosion, the author modified his technique using the vaginal flaps created during dissection of the anterior segment to close one over the other.

The author concludes from his experience that mesh reinforcement is an effective treatment for severe recurrent prolapse of the anterior midvaginal wall, but should not be used as a primary repair.

Grody (20827, discussion) prefers a double-layered Mersilene mesh anchored with rapidly absorbable synthetic suture. He does not perform a urethropexy, but uses deep pubovesicocervical paracystourethral fibromuscular flaps in a sling-like fashion.

As a reinforcement of the anterior colporrhaphy, Flood et al (22910) routinely used a Marlex mesh, 4 cms long and 1 cm wide, placed under the vesicourethral junction and secured at the level of the bladder neck with four absorbable sutures in order to prevent migration of the mesh in the immediate postoperative period. During the follow-up time of 3.2 years (mean), no patient experienced recurrence. Only three patients (out of 142) experienced mesh erosion, which developed at 3 months, 4 years and 7 years, respectively. All were cured by simple trimming of the exposed mesh area. There were no infections observed, nor any case of erosion into the bladder or urethra. This complication rate is low, compared to mesh-related complications reported in the literature otherwise: (22210)

10% sinus tract formation (Gore-Tex)

Erosions (9% with Marlex, Mersilene, Gore-Tex, 11% with Teflon)

Urethral erosion 4% (Marlex)

Fistula 1.4%

Mesh removal rate 6%

Overall revision and removal rate among 961 synthetic suburethral slings was 7,3%

After sling procedures with Gore Tex up to 35% removal rate

Overall revision and removal rate among 592 sacrocolpopexy was 2,7%.

### **2.8.2 Composite meshes**

Villet et al. (20414) used a Vicryl-Dacron composite mesh for treatment of vaginal prolapse for sacrospinous fixation in 32 patients with good results. No infectious complication was observed and the material was perfectly tolerated. Dubuisson and Chapron (23449) confirmed the good results with the composite mesh performing the sacrospinous fixation laparoscopically in 2 patients.

Migliari and Usai (23679) who used the same type of composite material in 15 patients with grade IV cystocele as an addition to the classic 4-corner bladder base and neck suspension procedure, observed new onset enterorectocele in 2 patients after 6 months following surgery, as a procedure-related complication. There were no mesh-related complications.

### **2.8.3 Absorbable mesh**

To treat cystocele grade IV, Albo et al. (24784) used Dexon-mesh to reduce the central defect of the cystocele in 58 patients of whom 92% had no recurrence during the follow-up (range 6-24 months. Lyons and Winer (18548) describe the use of Vicryl mesh for laparoscopic colposacropexy.

Other authors, however, are concerned to use absorbable mesh – such as Vicryl mesh or Dexon mesh - when extended support is desired (22210).

### 3. Annex

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